Outcomes of integrated management versus specialized care for patients with type 2 diabetes: An observational study

Outcomes of integrated management versus specialized care for patients with type 2 diabetes: An observational study

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ABSTRACT

Aims: To compare type 2 diabetes (T2D) patients included in a Diabetes Integrated Management (DIM) program with those followed in Diabetes Specialized Care (DSC), investigating differences in general characteristics, changes in clinical outcomes, and factors related with the inclusion in the DIM program.

Methods: T2D patients living in the ASLTO3 district and included into the DIM program, a shared disease management between general practitioners and diabetes specialists, from 2008 to 2014 were compared with T2D patients living in the same district and in charge of the local DSC. Demographic, anthropometric and clinical data for both groups of patients were obtained from the electronic records of DSC.

Results: 1326 DIM patients were compared with 3494 DSC patients. A higher proportion of females was observed among DIM patients than among DSC patients. DIM patients were older, more frequently in therapy with diet only or with oral hypoglycemic, and had HbA1c and creatinine lower than DSC patients. The analyses of changes in clinical parameters during the study period showed a good and statistically significant improvement of most parameters, independently of the inclusion in DIM or DSC, with the exception of creatinine level.

Conclusions: Integrated Management is an efficient and effective way to achieve good longterm clinical outcomes for patients with diabetes.

1. Introduction

Type 2 diabetes mellitus (T2D) is a chronic condition responsible for 1.5 million deaths and 20 million disability adjusted years lost yearly, and increasing costs for the National Health Systems worldwide [18,28,30].

Patients with diabetes need continuous care and monitoring of the disease, which are generally provided by diabetes specialized centers (DSC). It is indeed commonly believed that care in DSC assures good outcomes [1].

However, in recent years the need to limit health care costs for chronic conditions experienced in most western countries has promoted the opportunity to shift the care of diabetes patients to general practitioners following an integrated care model [26,27]. Moreover, several studies suggested that specialized centers do not allow better outcomes for patients with diabetes than primary care generalists [2,6,9–11,13,16,19,23,25].

In Italy, T2D accounts for more than 3 million patients and the number increases each year [7,14,17]. Since 2003, the Ministry of Health included diabetes among the priority areas of intervention of the National Health Plan committing the regions to fight the disease through the activities of the National Health Service. The 2005–2007 National Prevention Plan promoted the adoption of chronic disease management programs across the country. The ‘‘Gaining Health” project, a comprehensive strategy for fighting non-communicable diseases, was then launched in accordance with the countries of the WHO Regional Office Europe and the European Union. In this

framework, the Italian Centre for Disease Prevention and Control, and the Istituto Superiore di Sanita` promoted the IGEA initiative, a strategy for implementing chronic disease integrated management interventions for people with diabetes reorienting healthcare services to prevent disabilities, favouring primary care, and increasing the self management of persons with chronic diseases [12,15].
Piedmont is a 4.4million inhabitants region in North West of Italy. Patients with diabetes are about 283,000, and most are affected by T2D [3]. Diabetes care and assistance are in charge of 25 specialized centers and of general practitioners (GPs) of the National Health System. Since 2008, a regional protocol promoted the shift of diabetes care from specialized centers to GPs. Patients with T2D in stable metabolic control can be included in the Diabetes Integrated Management (DIM) model of care: they are followed by their GPs with regular laboratory controls and quarterly visits, and they access DSC on a yearly base or in case of acute conditions. The participation of the GPs to the DIM protocol is on a voluntary basis, with the provision of an economic incentive per each patient included in the program [21].
The aim of this study was to compare the T2D patients of the ASLTO3 Health Care district in northwest Italy included in the DIM program with those followed by DSC by investigating differences in general characteristics at baseline and at follow-up, changes in clinical outcomes, and factors related with the inclusion in the DIM program.

2. Subjects, materials and methods

The list of T2D patients living in the ASLTO3 Health Care district and included into the DIM program from 1st September 2008 to 31st December 2014 was extracted from the DIM Regional Database. Data extraction was limited to 31st December 2014 in order to have at least one year follow-up for all patients. Patients were included in the DIM program by their GPs, according to the inclusion and exclusion criteria as defined by the regional protocol. Inclusion criteria: age >18 years; type 2 diabetes. Exclusion criteria: type 1 diabetes; gestational diabetes; secondary diabetes.
Data on T2D patients living in the ASLTO3 Health Care district and in charge of the local DSC (San Luigi Gonzaga University Hospital Diabetes Outpatient Clinic), satisfying inclusion and exclusion criteria for the DIM program but not included into the DIM program, were extracted from the DSC database.
To ensure the comparability of DIM and DSC groups, only patients with a visit at San Luigi Gonzaga DSC after 1st September 2007 (baseline) and at least one follow-up visit by 31st December 2015 were considered. Following these criteria, 1326 DIM patients in charge of 150 general practitioners and 3494 T2D patients in charge of the San Luigi Gonzaga DSC but not included in DIM were available for the analyses.
Demographic, anthropometric and clinical data for both groups of patients were obtained from the electronic records of San Luigi Gonzaga DSC that included data on baseline and yearly follow-ups of the DIM patients and data on scheduled visits of the other DSC T2D patients not included in the DIM program. For all patients information was retrieved on demographic data, date of T2D diagnosis, date of first and last control at the DSC, drug treatment, clinical measurements at baseline and at last control, including: height, weight, BMI, systolic and diastolic blood pressure, HbA1c, creatinine, triglycerides, total cholesterol, HDL cholesterol, non-HDL cholesterol, and LDL cholesterol according to Friedewald's equation [8].

2.1. Statistical analysis

Characteristics of DIM and DSC patients at first visit were described through proportions, means and SD. Differences between the groups in socio-demographic and clinical characteristics at first visit were analyzed through univariate and multivariate logistic regression analyses calculating Crude and Adjusted Odds Ratios (OR) and 95% Confidence Intervals, thus identifying factors related with the inclusion in DIM vs DSC. Significance level was set at $p < 0.05$. After checking co-

linearity among variables, all indicators statistically significant in the univariate analysis were included in the adjusted model. Variables correlated with r > 0.60 were excluded from the model. Weight and BMI were correlated with r = 0.71; LDL cholesterol and non-HDL cholesterol were correlated with total cholesterol (r = 0.72 and r = 0.76 respectively); LDL cholesterol and non-HDL cholesterol were correlated each other (r = 0.82). Among these variables, BMI and non-HDL cholesterol were chosen for the inclusion in the model. Gender, age at diagnosis, therapy, BMI, HbA1c, triglycerides, HDL cholesterol, non-HDL cholesterol and creatinine were finally included in the model.
Normality distribution of clinical indicators was tested using the Kolgomorov-Smirnov test. All variables violated the normality assumption. Therefore, differences between groups were assessed through Wilcoxon sum rank test. Differences in changes of clinical indicators in the two groups were then compared calculating % change at follow-up out of the baseline level, and the differences from first to last visit were assessed through Wilcoxon signed rank test.

3. Results

3.1. Baseline characteristics and differences between DIM and DSC patients

Baseline general and clinical characteristics of patients in DIM and DSC are described in Table 1.
In both groups, the majority of patients were males (57.6% vs 42.3%), and the proportion of males was higher in the DSC (58.9%) vs the DIM group (54.3%).
Patients in DIM were slightly older than those in DSC (mean age 58.2 vs 56.0 years) and more frequently were in therapy with diet only (26% vs 14.7%) or with oral hypoglycemic drugs (56.3% vs 52.3%), whilst less frequently took insulin (10.4% vs 21.4%) or the association of insulin and hypoglycemic drugs (7.4% vs 11.5%).
DIM patients weighted less than DSC ones (mean weight 78.8 vs 80.7 kg) and their BMI was lower (mean 29.2 vs 29.7). According to BMI, a higher proportion of patients affected by severe obesity were observed among DSC patients (14.2% vs 11.4%).
HbA1c% was lower among DIM patients (mean 7.4%-54 mmol/mol vs 7.9%-63 mmol/mol). A higher proportion of DIM patients had values lower than 7.5%-58 mmol/mol (69.3% vs 56.2%) and a lower proportion had values higher than 9.5%-80 mmol/mol (8.9% vs 15.7%).
As regards creatinine, baseline mean levels were similar but a higher proportion of DIM than DSC patients showed values <1.1 mg/dl (85.7% vs 79.4%).
No differences were observed between the two groups in diastolic blood pressure. On the contrary, a higher proportion of DIM subjects had normal (120–139 mmHg) systolic blood pressure (51.4% vs 47.8% of DSC patients).
For both DIM and DSC groups, the majority of patients showed a good control of triglycerides; however, in DSC group a higher proportion of patients with values >200 mg/dl was observed (19.9% vs 16%). Also for the other parameters of lipid control no big differences were observed between the two groups, apart from a slightly lower proportion of patients with high HDL cholesterol values among DSC vs DIM subjects (16.7% vs 18.5%).
In conclusion, DIM patients apparently showed at baseline a lower severity of clinical conditions and a better glycemic control than DSC patients.

3.2. Factors related to the inclusion in DIM vs DSC

Univariate analysis showed that female gender, age at T2D diagnosis older than 50 years, being in therapy with diet only, a lower weight and BMI, HbA1c <6.5%-48 mmol/mol, creatinine values <1.1 mg/dl, triglycerides <200 mg/dl, and HDL cholesterol >40 mg/dl were significantly related with the inclusion in DIM vs DSC (Table 2).
Female gender, older age at T2D diagnosis, being in therapy with diet only, lower values of HbA1c and creatinine were confirmed by the multivariate adjusted analyses as factors significantly related

with the probability to be included in DIM vs DSC model of care. By converse, males, subjects on oral hypoglycemic drugs, insulin or the association of oral hypoglycemic drugs and insulin, having HbA1c >8.5%-69 mmol/mol and creatinine >1.1 mg/dl, had a lower probability to be included in DIM by their GPs (Table 2).

3.3. Changes in clinical parameters from baseline to follow-up

The analyses of changes in clinical parameters between first and last follow-up visit during the study period showed a good and statistically significant improvement of most parameters in the entire study population, independently of the inclusion in DIM or DSC model of care (Figs. 1 and 2, Table 3).
The exception was creatinine level, that worsened both among patients in DIM (+1.1% of the starting level) and among those in DSC (+4.0% of the starting level); the difference in worsening between the groups was not statistically significantly ($p = 0.41$) (Table 3). In both groups, the worsening of creatinine was not statistically significant ($p = 0.66$ for DIM patients, and $p = 0.15$ for DSC patients) (Fig. 2).
On the contrary, consistent with the worst baseline level of the DSC group, the improvement of HbA1c was significantly higher among DSC patients than among DIM ones (5.8% of the starting level vs 4.0%, $p = 0.056$) (Table 3). In both groups the improvement of HbA1c was statistically significant (Fig. 1).

4. Discussion

In our study, a higher proportion of females was observed among patients included by their GPs in DIM than among patients under DSC. Patients in DIM were of older age, more frequently in therapy with diet only or with oral hypoglycemic, and with baseline level of HbA1c and creatinine lower than patients under DSC. Overall, DIM patients showed at baseline a lower severity of clinical conditions and a better glycemic control than DSC patients. The analyses of changes in clinical parameters during the study period showed a good and statistically significant improvement of most parameters, independently of the inclusion in DIM or DSC, with the exception of creatinine level that worsened (although not significantly) in both groups, and HbA1c that improved more among DSC than DIM patients. The last results are expected, considering the different characteristics of patients in the two groups at baseline and the expected worsening of the disease.
The lower severity of diabetes in patients included in DIM is consistent with previous studies: it is a common and expected observation that patients followed by specialized clinics have a more severe disease than those followed by their GPs.
Previous studies reported a higher proportion of males, younger age, more frequent therapy with insulin and overall worse health status among DSC vs DIM patients [4,5,13,16,20]. In a historical period where governments try to reduce health costs introducing new models of care based on integrated actions between general practitioners and specialized professionals, such result is actually desired. It reduces the overload of patients at DSC, shifting patients without complications and in good metabolic control to GPs: this appears as a rational choice that helps specialized clinics to dedicate to patients with more severe disease. Moreover, the Italian model of integrated care, as encouraged by the Ministry of Health, includes yearly controls, or more if needed, at DSC, thus promoting the integration of care and the communication between GPs and DSC: if applied, such actions improve continuity of care. The promotion of this model has several advantages for the national and regional public health system: reduction of costs, improvement of appropriateness and reduction of waiting lists. Previous studies comparing specialized with not specialized or integrated care showed the similarity of outcomes for diabetes patients followed by one or the other professionals [6,9–11,13,16,19,25], or even better outcomes for the integrated management scheme [2,23,29]. Our study confirms these findings: outcomes did not differ among patients in DIM or DSC aside from worsening of creatinine and improvement of HbA1c, two results that are explained

by the differences in clinical parameters and severity of the conditions at baseline. It is commonly observed, independently from the scheme of care applied, that metabolic control improves soon after the patients is diagnosed and treated [11,13,22–25]; that patients with poorly controlled diabetes benefit the most [22,24]; and that, despite overall improvement of clinical parameters, diabetes care is unable to prevent increase of creatinine over time [13]. In light of effectiveness of the health care action, it appears of great importance that patients show an immediate improvement of clinical conditions and parameters as soon as they are taken in charge. At long follow-up this will end in a lower number of hospital admissions, lower complication rates, and longer survival [2,29].
For the overall functioning of the system and the achievement of positive clinical outcomes, a training of GPs to the new model of care, the provision of specific guidelines, and the use of new technologies to share information can be useful.
Our study has some strength. All patients treated in DIM in the district of ASLTO3 were compared to all patients treated in DSC in the same district, so that the generalizability of the findings is ensured. The number of patients included in the study was high. The clinical data were complete for both populations. Outcomes data were available at long follow-up. Differences between the two samples were investigated through a multivariate model, adjusting for confounding factors.
Our study has also some limits. First of all, the observational design does not allow evaluating the effectiveness of the DIM versus standard DSC care. Selection of less severe patients for the inclusion in DIM ca not be completely adjusted in multivariate analysis, and residual confounding may be present. This bias could have masked the possible superior results of DSC. Finally, we could not analyse strong outcomes such as mortality and hospital accesses.
In conclusion, our study confirms that the introduction of an integrated model of care is an efficient way to ensure good quality of diabetes care. The increasing burden of diabetes experienced by western countries calls for a more efficient and coordinated health care delivery. The social and economic costs related to chronic complications need timely effective prevention and care. The consistency of positive outcomes of integrated care provided by GPs and specialized care is reassuring and confirms the crucial role of GPs in helping the system to curb costs and inappropriate use of specialized care, assuring good long-term clinical outcomes for patients with diabetes.

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Table 1 – General and clinical characteristics of patients in Diabetes Integrated Management and Diabetes Specialized Care at baseline.

Characteristics		DIM n = 1326 %	DSC n = 3494 %	Total n = 4820 %
Gender	Female	45.7	41.0	42.3
	Male	54.3	58.9	57.6
Age at diagnosis (years)	Mean ± SD	58.2 ± 10.7	56.0 ± 11.3	56.6 ± 11.2
	<40	5.3	7.8	7.1
	40–49	14.6	21.9	19.8
	50–59	35.0	33.8	34.1
	60–69	30.7	26.0	27.2
	70–79	13.4	9.4	10.5
	>79	0.8	1.2	1.2
Therapy	Diet	26.0	14.7	17.8
	Oral hypoglycemic drugs	56.3	52.3	53.4
	Insulin	10.4	21.4	18.4
	Oral hypoglycl. drugs + Insulin	7.4	11.5	10.4
Weight (kg)	Mean ± SD	78.8 ± 14.9	80.7 ± 16.0	80.2 ± 15.8
	<60	6.2	6.8	7.2
	60–69	19.0	16.6	17.3
	70–79	28.2	27.6	27.8
	80–89	24.1	23.7	23.8
	>89	20.4	25.3	23.9
BMI (kg/m^2)	Mean ± SD	29.2 ± 4.8	29.7 ± 5.3	29.6 ± 5.1
	<25.0	17.7	17.0	17.2
	25.0–29.9	41.8	41.3	41.5
	30.0–34.9	29.1	27.5	27.9
	35.0–39.9	8.8	9.8	9.5
	>39.9	2.6	4.4	3.9
HbA1c% (mmol/mol)	Mean ± SD	7.4 (54) ± 1.0	7.9 (63) ± 1.9	7.7 (61) ± 1.8
	<6.6 (49)	31.0	23.3	25.4
	6.6 (49)–7.5 (58)	38.3	32.9	34.4
	7.6 (60)–8.5 (69)	15.3	18.6	17.7
	8.6 (70)–9.5 (80)	6.4	9.4	8.6
	9.6 (81)–10.5 (91)	3.0	5.8	5.1
	10.6 (92)–11.5 (102)	2.8	3.8	3.5
	>11.5 (102)	3.1	6.1	5.3
Creatinine (mg/dl)	Mean ± SD	0.9 ± 0.3	1.0 ± 0.4	0.9 ± 0.4
	<1.1	85.7	79.4	81.1
	1.1–2.0	13.9	19.9	18.3
	>2.0	0.4	0.7	0.6
Diastolic blood pressure (mmHg)	Mean ± SD	77.9 ± 7.6	78.0 ± 7.9	78.0 ± 7.8
	<80	38.8	38.0	38.2
	80–89	49.5	49.3	49.4
	90–99	11.7	12.7	12.4
	>99	1.7	1.7	1.7
Systolic blood pressure (mmHg)	Mean ± SD	135.3 ± 12.9	136.0 ± 13.5	135.8 ± 13.4
	<120	4.3	4.3	4.3
	120–139	51.4	47.8	48.9
	140–159	37.7	40.4	39.7
	>159	6.6	7.4	7.2
Triglycerides (mg/dl)	Mean ± SD	146.2 ± 85.3	153.0 ± 95.8	151.2 ± 93.1
	<150	65.3	61.9	62.9
	150–199	18.8	18.1	18.3
	200–499	14.9	18.6	17.6
	>500	1.1	1.3	1.3

Table 1 – (Continued)

Characteristics		DIM n = 1326 %	DSC n = 3494 %	Total n = 4820 %
HDL cholesterol (mg/dl)	Mean ± SD	49.2 ± 13.6	48.1 ± 13.1	48.4 ± 13.3
	<40	22.5	25.9	25.0
	40–59	59.0	57.4	57.8
	>59	18.5	16.7	17.2
LDL cholesterol (mg/dl)	Mean ± SD	120.5 ± 37.6	119.8 ± 54.4	120.0 ± 50.4
	<71	7.8	8.0	8.0
	71–100	22.8	25.4	24.7
	101–129	32.4	31.0	31.4
	130–159	22.7	21.5	21.8
	160–189	10.5	9.8	10.0
	>189	3.8	4.1	4.0
Non-HDL cholesterol (mg/dl)	Mean ± SD	149.7 ± 40.9	150.0 ± 43.6	150.0 ± 42.9
	<94	6.7	6.4	6.5
	94–124	21.0	23.8	23.1
	125–156	32.0	30.5	30.9
	157–189	25.0	22.7	23.3
	190–222	10.7	10.7	10.7
	>222	4.4	5.8	5.4
Total cholesterol (mg/dl)	Mean ± SD	199.0 ± 42.8	198.2 ± 44.9	198.4 ± 44.3
	<100	0.2	0.3	0.2
	100–200	53.6	56.3	55.6
	201–300	44.0	41.2	42.0
	>300	2.1	2.2	2.1

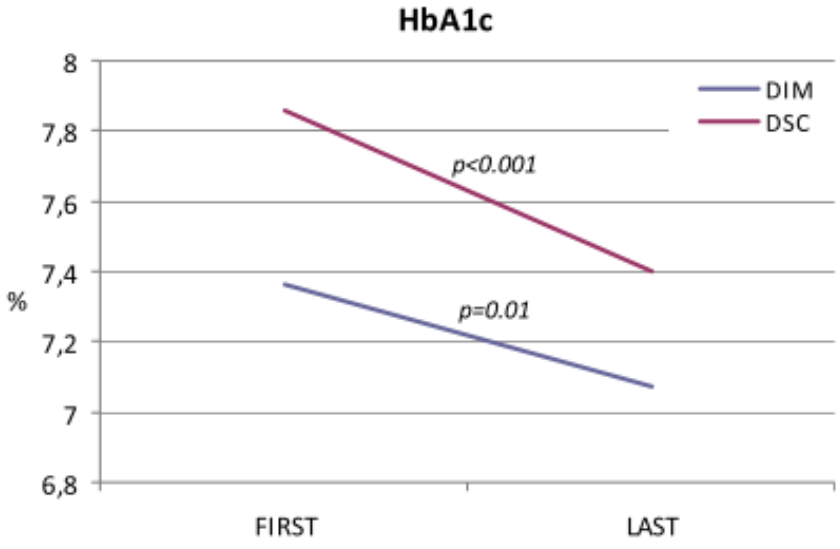

Fig. 1 – Improvement of HbA1c in DIM and DSC patients.

Table 2 – Factors related with the inclusion in DIM vs DSC, crude and adjusted ORs.

Characteristics		Crude Odds Ratio (95% CI)	*p* value	Adjusted Odds Ratio (95% CI)	*p* value
Gender	Female	1.00		1.00	
	Male	0.83 (0.73–0.94)	0.003	0.86 (0.74–0.99)	0.037
Age at diagnosis (years)	<50	1.00		1.00	
	50–59	1.53 (1.28–1.81)	<0.001	1.30 (1.09–1.55)	0.004
	60–69	1.75 (1.46–2.09)	<0.001	1.37 (1.14–1.65)	0.001
	>69	1.98 (1.59–2.47)	<0.001	1.43 (1.13–1.81)	0.003
Therapy	Diet	1.00		1.00	
	Oral hypogl.	0.60 (0.51–0.71)	<0.001	0.68 (0.57–0.80)	<0.001
	Insulin	0.25 (0.21–0.34)	<0.001	0.37 (0.29–0.47)	<0.001
	Oral hypogl. + Insulin	0.36 (0.28–0.47)	<0.001	0.46 (0.35–0.60)	<0.001
Weight (kg)	<70	1.00		–	–
	70–79	0.87 (0.74–1.03)	n.s.	–	–
	80–89	0.87 (0.73–1.04)	n.s.	–	–
	>89	0.69 (0.57–0.83)	<0.001	–	–
BMI (kg/m^2)	<25.0	1.00		1.00	
	25.0–29.9	0.97 (0.81–1.16)	n.s.	0.93 (0.77–1.13)	n.s.
	30.0–34.9	1.02 (0.84–1.23)	n.s.	1.04 (0.85–1.27)	n.s.
	>34.9	0.77 (0.60–0.97)	0.029	0.80 (0.62–1.02)	n.s.
HbA1c% (mmol/mol)	<6.5 (48)	1.00		1.00	
	6.6 (49)–7.5 (58)	0.87 (0.74–1.01)	n.s.	0.98 (0.83–1.15)	n.s.
	7.6 (60)–8.5 (69)	0.61 (0.50–0.74)	<0.001	0.85 (0.69–1.05)	n.s.
	>8.5 (69)	0.45 (0.37–0.55)	<0.001	0.67 (0.54–0.83)	<0.001
Creatinine (mg/dl)	<1.1	1.00		1.00	
	1.1–2.0	0.64 (0.50–0.77)	<0.001	0.69 (0.57–0.83)	<0.001
	>2.0	0.53 (0.20–1.39)	n.s.	0.75 (0.27–2.05)	n.s.
Diastolic blood pressure (mmHg)	<80	1.00		–	–
	80–89	0.98 (0.86–1.12)	n.s.	–	–
	90–99	0.89 (0.71–1.21)	n.s.	–	–
	>99	0.94 (0.57–1.56)	n.s.	–	–
Systolic blood pressure (mmHg)	<120	1.00		–	–
	120–139	1.07 (0.78–1.47)	n.s.	–	–
	140–159	0.93 (0.67–1.28)	n.s.	–	–
	>159	0.88 (0.59–1.30)	n.s.	–	–
Triglycerides (mg/dl)	<150	1.00		1.00	
	150–199	0.98 (0.83–1.16)	n.s.	0.98 (0.82–1.17)	n.s.
	>199	0.75 (0.63–0.89)	0.002	0.82 (0.67–1.00)	n.s.
HDL cholesterol (mg/dl)	<40	1.00		1.00	
	40–59	1.18 (1.01–1.37)	0.035	0.98 (0.83–1.15)	n.s.
	>59	1.26 (1.03–1.54)	0.019	0.95 (0.76–1.19)	n.s.
LDL cholesterol (mg/dl)	<101	1.00		–	–
	101–129	1.14 (0.97–1.33)	n.s.	–	–
	>129	1.13 (0.97–1.32)	n.s.	–	–
Non-HDL cholesterol (mg/dl)	<125	1.00		1.00	
	125–156	1.14 (0.97–1.34)	n.s.	1.12 (0.94–1.32)	n.s.
	>156	1.11 (0.95–1.30)	n.s.	1.11 (0.94–1.32)	n.s.
Total cholesterol (mg/dl)	<200	1.00		–	–
	200–300	1.12 (0.98–1.27)	n.s.	–	–
	>300	1.00 (0.64–1.56)	n.s.	–	–

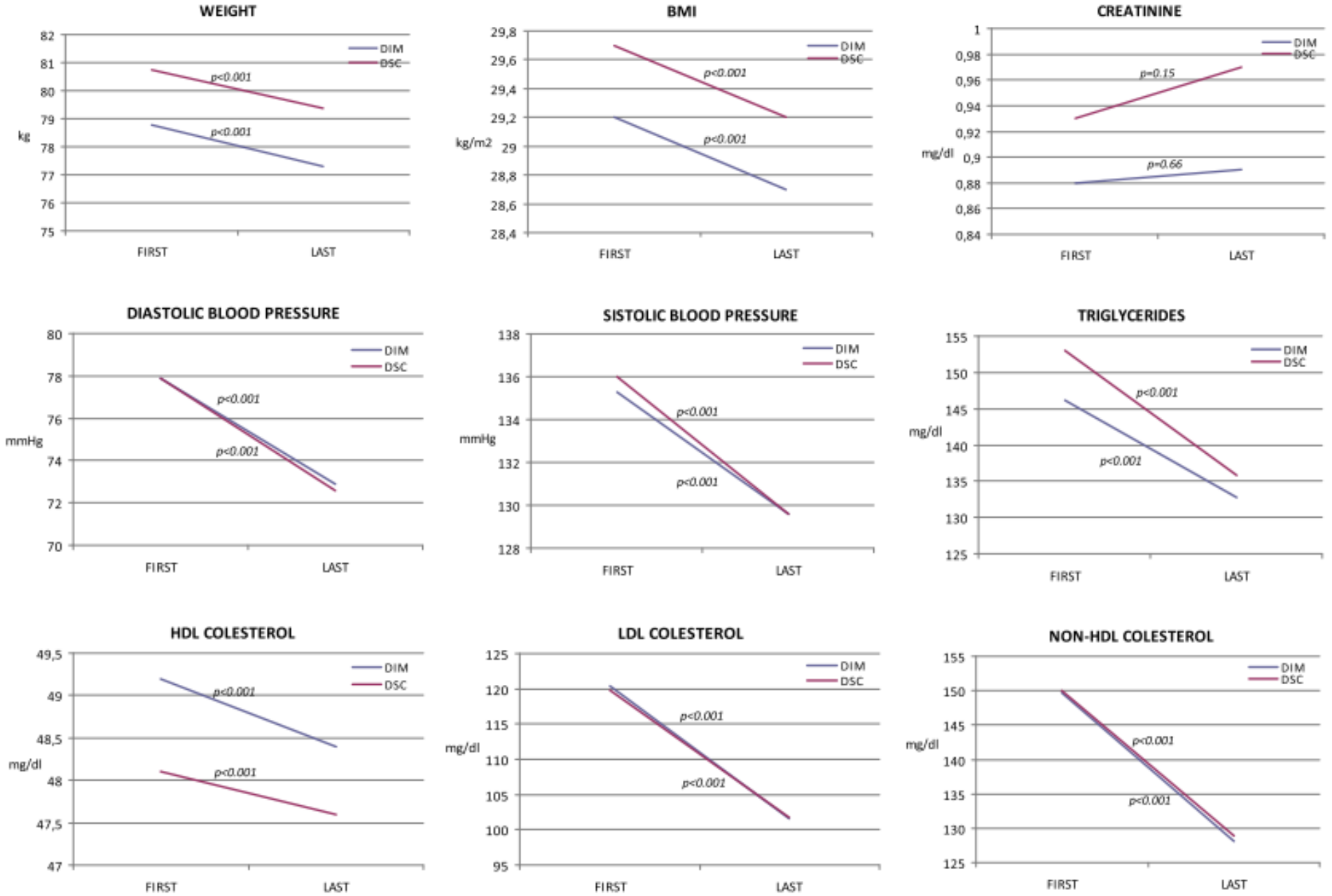

Fig. 2 – Improvement of clinical parameters among DIM and DSC patients.